

K013990



Edwards

FEB 27 2002

510(k) Summary

Submitter: Edwards Lifesciences LLC

Contact Person: Lucinda Stockert, Regulatory Associate

Date Prepared: February 14, 2000

Trade name: LifeStitch Suturing Device

Classification name: Nonabsorbable poly(ethylene terephthalate) surgical suture

Predicate Devices:

- Auto Suture™ ENDO STITCH™ Disposable Suturing Device (K972911)
- *Sew-Right® SR•5™* Precision Remote Suturing Device (K011016)
- Novafil™ suture material (K990952)

Device Description: The Edwards LifeStitch Suturing Device is a sterile, single use only device that uses aspiration and mechanically activated surgical needles to approximate and place interrupted sutures into soft tissue. The LifeStitch suturing device has a handle/housing attached to a 30F (10 mm) barrel that is approximately 23 cm in length. Attached to the distal tip of the barrel is a needle holder that contains four stainless steel needles with pre-attached 4-0 nonabsorbable, monofilament polybutester surgical suture. Sterile tubing is provided for connection between the device and a vacuum source. The LifeStitch Suturing Device is provided in a kit that also contains an optional-use knot pusher/cutter for lowering hand-tied suture knots and cutting suture tails.

Indications for Use: The LifeStitch Suturing Device is used for the approximation of soft tissue.

Comparative Analysis: It has been demonstrated that the LifeStitch Suturing Device is comparable to the predicate devices in design, intended use, materials, and principle of operation.

Functional/Safety Testing: The LifeStitch Suturing Device has successfully completed design verification testing.

Conclusion: The LifeStitch Suturing Device is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2002

Ms. Lucinda Stockert
Regulatory Affairs Associate
Edwards Lifesciences LLC
One Edwards Way
Irvine, California 92614

Re: K013990

Trade/Device Name: LifeStitch Suturing Device
Regulation Number: 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: November 30, 2001
Received: December 3, 2001

Dear Ms. Stockert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

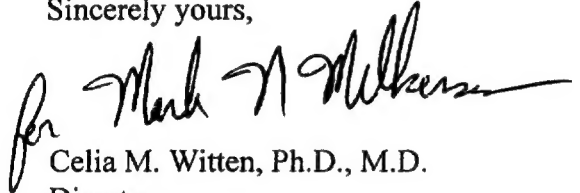
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K013990:

Device Name: LifeStitch Suturing Device

Indications for Use:

The Edwards Lifesciences LifeStitch Suturing Device is used for the approximation of soft tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

for Mark A. Melkus
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number _____

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